PSJ3

Exhibit 408

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

September 13, 2012

IN THE MATTER OF

Walgreen Co.
15998 Walgreens Drive
Jupiter, Florida 33478

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Walgreen Corporation ("Walgreens" or "Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Walgreens an opportunity to show cause before DEA in Arlington, Virginia, or a location designated by the Administrative Law Judge, on November 13, 2012 (if Walgreens requests such a hearing), as to why DEA should not revoke Walgreens's DEA Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(b) & (e), because Walgreens' continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(b) & (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following nonexhaustive summary of facts and law (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia* in this context.)

1. Walgreens' Jupiter Florida Distribution Center is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478. DEA Certificate of Registration RW0277752 expires by its terms on May 31, 2013. The Jupiter Distribution Center is one of 12 Distribution Centers owned and operated by the Walgreen Corporation,

headquartered in Deerfield, Illinois. Walgreens also operates more than 7800 Walgreens retail pharmacies in the United States.

2. Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The drugs most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone; Schedule IV benzodiazepines such as alprazolam, and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these drugs are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. *See East Main Street Pharmacy*, 75 Fed. Reg, 66149, 66153, (2010); *Paul H. Volkman*, 73 FR 30630, 30633-34, 30639 (2008), *pet. for rev. denied*, *Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).

3. Oxycodone is a dangerously addictive Schedule II controlled substance which is known to be highly abused and diverted in the State of Florida. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the state of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam.)

4. Since 2009, Walgreens' Jupiter, Florida Distribution Center has been the single largest distributor of oxycodone products in Florida. At about the same time as the abuse of prescription drugs became an epidemic in Florida, Walgreens' Florida retail pharmacies, supplied by Respondent, commanded an increasingly large percentage of the state's growing oxycodone business. In 2010, only 3 Walgreens retail pharmacies were in the top 100 purchasers of oxycodone within Florida. In 2011, 38 Walgreens pharmacies made the top 100 and 6 were in the top 10. Through May 2012, 44 Walgreens pharmacies are in the top 100 oxycodone purchasers, all of them supplied by Respondent.

5. According to DEA records, in 2011, Walgreens operated 7,862 retail pharmacies in the United States. Sixteen of the top 25 largest Walgreens retail oxycodone purchasers, including the top 6 purchasers, were in Florida and supplied by Respondent. The following table shows these 6 stores and their yearly oxycodone purchases for 2009 through 2011:

Store # Location	Oxycodone Purchases by Dosage Unit 2009	2010	2011
1. 03629 Hudson, FL	388,100	913,900	2,211,700
2. 03099 Ft. Myers, FL	95,800	496,100	2,165,900
3. 06997 Oviedo, FL	80,900	223,500	1,684,900
4. 03836 Port Richey, FL	344,000	849,000	1,406,000
5. 04391 Ft. Pierce, FL	250,000	881,400	1,329,600
6. 04727 Ft. Pierce, FL	153,500	507,100	1,192,000

6. An ongoing DEA investigation of Respondent's distribution practices and policies, combined with both a general examination of dispensing at Walgreens Florida pharmacies as well as a detailed investigation of the dispensing practices at the six pharmacies identified above, demonstrates that Respondent has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). Respondent failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007) (revocation based in part on the respondent's recurring distributions of extraordinary quantities of controlled substances to entities that likely diverted the controlled substances by filling unlawful prescriptions, as well as the respondent's failure to conduct due diligence sufficient to protect against the diversion of the controlled substances it distributed).

7. DEA's investigation of Respondent also revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b) (distributors are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances . . . suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,502 (finding that the respondent repeatedly violated federal regulations by failing to report suspicious orders). Walgreens knew or should have known about their obligations to report suspicious orders, as such obligations were spelled out in detail in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. The purpose and proper implementation of suspicious order reporting programs was further discussed in the industry's own trade association, the

Healthcare Distribution Management Association (HDMA), in "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" published in 2008.[1]

8. Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies. *See* 21 C.F.R. § 1301.74(b); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007).

9. Respondent's practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled "Suspicious Control Drug Orders." Two reports were provided, one for suspicious orders of Schedule II drugs, another for suspicious orders of drugs in Schedules III through V. These reports were transmitted on Respondent's behalf from Walgreens Corporate headquarters in Deerfield, Illinois. Respondent's suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico. The reports are based on a formula that assigns an average monthly order for a particular drug, which is then multiplied by a "DEA factor" (which is always 3, regardless of the drug or the average order amount), resulting in a "Trigger" amount, above which orders for the month are reported as suspicious, along with a listing of all orders placed for the particular drug by the reported pharmacy for the month in which the "Trigger" amount was exceeded. This report from the Jupiter Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area.

10. As made clear in 21 CFR §1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded. As such, Respondent's reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title Respondent attached to these reports.

[1] See http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf.

11. A review of the documents Respondent provided as evidence of its "due diligence" on the above listed six pharmacies, demonstrates that Respondent failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels. In response to DEA requests, Respondent has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.

12. Respondent's employee with overall responsibility for Schedule II drug operations (the "CII Function Manager"), raised questions within the corporation about what she correctly identified as unusually large orders for Schedule II narcotics placed regularly by several customer pharmacies. Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy. For example:

    a. In January 2011, Jupiter's CII Function Manager expressed concern about the enormous volume of 30 mg oxycodone being ordered by three stores, Walgreens #'s 7298, 3836, and 5018, concluding in an email to the "Manager, Rx Inventory Drug Stores" at Walgreens' Corporate Headquarters in Deerfield, Illinois, that she felt the stores needed "to justify the large quantity." With regard to store # 3836 in Port Richey, Florida, she noted that Respondent had shipped this store 3271 bottles of 100 count 30 mg oxycodone (i.e., 327,100 dosage units) in the 40 day period from 12/1/10 to 1/10/11, causing her to question *"how they can even house this many bottle[s]."* She then inquired of the same corporate manager: *"How do we go about checking the validity of these orders?"*

    b. Despite having raised these concerns from the distributor to a supervisor at corporate headquarters, none of these orders were reported as suspicious and there appears to have been no other inquiry conducted into the circumstances of the enormous amount of narcotics being shipped to store # 3836 in Port Richey, a town of less than 3000 people in a county with a population of only approximately 475,000. Despite the fact that a distribution center manager had raised questions about this store's ordering volume to a corporate manager in January 2011, the very next month, Respondent filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy. Again, there is no evidence of any due diligence conducted by Respondent or anyone else within the corporation to verify the legitimacy of these orders in order to fulfill their obligation to maintain effective controls against diversion.

13. According to documents received from Walgreens Corporate Headquarters, on April 2, 2012, Walgreens revised its suspicious order policy, but made the policy retroactively effective to January 1, 2012. The policy states, in pertinent part, that "Effective calendar year 2012, the Controlled Substance Order Monitoring and Prevention System prevents suspicious control drugs from being shipped to the stores. In calendar year 2012, because of the program mentioned, suspicious control drug reports are no longer generated as their shipment is prevented by the system."

14. This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

15. Respondent's local DEA field office within the Miami Field Division has not received a suspicious order report for any orders placed in 2012, despite the fact that Respondent has received and shipped multiple orders this year that, using the criteria Walgreens employed in 2011, would have exceeded the trigger amount previously used to report these sales.

16. The available evidence suggests that Respondent's abdication of its responsibilities as an individual registrant was at least facilitated by a push from Walgreens Corporate headquarters to increase oxycodone sales at its Florida retail pharmacies, all of which received their Schedule II controlled substances from Respondent. I also note that during the relevant time herein, Walgreens had in effect compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy. This bonus program, combined with a concerted, corporate directed effort to increase oxycodone sales, served as an incentive for pharmacists and pharmacy technicians to ignore the "red flags" of diversion presented by these prescriptions, many of which, in the proper exercise of the pharmacist's corresponding responsibility under 21 CFR §1306.04(a), should have resulted in a refusal to fill.

    a. In July 2010, Walgreens' corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens' market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce.*" A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "*We also have stores doing about 1 a day. Are we turning away good customers?*"

    b. At roughly the same time as Walgreens' supervisors were urging its Florida pharmacies to increase their oxycodone sales, Florida enacted new laws to combat the prescription drug abuse problem, particularly the devastating effects of oxycodone and other abused drugs dispensed directly from rogue pain clinics, commonly known as "pill mills." These new laws went into effect on October 1, 2010 and severely restricted the ability of pain clinics and physicians to dispense controlled substances directly from the clinics. The purpose of these legislative changes was to stem the overwhelming tide of controlled substances being

diverted from pill mills and into illicit channels for sale and recreational abuse. As a result, Florida pharmacies and the distributors who served them knew or should have known that starting in late 2010, there would be a significant increase in requests to dispense pursuant to prescriptions issued by physicians associated with the pain clinics.

c. Walgreens store # 06997 in Oviedo, Florida, was ranked 444th on the above-referenced Walgreens' ranking of oxycodone sales generated at its Florida retail pharmacies, filling on average only 4 oxycodone prescriptions per day in June 2010. DEA tracks pharmacy activity not by prescriptions but by dosage units of a particular drug purchased by the pharmacy for retail sales. In 2010, the national average for oxycodone sales to retail pharmacies was 70,395 dosage units per year, or about 5,866 dosage units per month. This store's oxycodone sales began to increase drastically, as shown by the fact that in June 2010, Walgreens store #06997 purchased just 6,600 dosage units of oxycodone products. One year later, in June 2011, this same pharmacy purchased 169,700 dosage units of oxycodone.

d. Oviedo is a town of about 34,000 people and is home to two Walgreens retail pharmacies. Beginning in late 2010, these two pharmacies became the site of multiple arrests by the local police for drug offenses. The local Chief of Police began writing letters to the pharmacies after each arrest stemming from prescriptions they filled. These letters informed the pharmacy of the circumstances of the arrest and that the dispensed drugs were not being used for treatment. They further provided the pharmacy with the name and date of birth not only of the person whose prescription they filled, but also of others associated with the illegal distribution of the dispensed drugs. These letters then concluded with a request for the pharmacy's help in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.

e. The Oviedo Police Chief's concerns reached the highest levels of Walgreens' Loss Prevention Operations, with the Director of Divisional Loss Prevention noting in an email on January 28, 2011 that "*[e]vidently the Chief of Police is concerned that we are filling too many C2 prescriptions.... From what I've been told, he is referencing 100 plus incidents/arrests in his jurisdiction.*" Walgreens' response was to "*take a look at this market . . . and see if we have an increase in dispensing.*"

f. The Oviedo Police Chief convened a meeting with Walgreens Loss Prevention officials on February 10, 2011, in an effort to further bring awareness of the problems he was seeing at their stores and to brief them on the number of arrests at each location. On March 15, 2011, he sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo "*has seen the parking lots of your stores become a bastion of illegal drug sales and drug use*" where once the prescriptions are filled, "*the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies.*"

g. Despite being informed at the highest levels of ongoing diversion and drug-related criminal activity directly stemming from dispensing at these pharmacies, and bearing in mind that the average U.S. retail pharmacy in 2011 purchased only 73,000 dosage units of *all formulations* of oxycodone *for the entire year*, the Walgreens corporation, through Respondent, responded to this information about one of its stores by shipping the following quantities of 30 milligram formulation oxycodone to Oviedo store 06997:

(i) February 2011	75,300 dosage units
(ii) March 2011	72,900 dosage units
(iii) April 2011	101,700 dosage units
(iv) May 2011	133,900 dosage units
(v) June 2011	115,200 dosage units
(vi) July 2011	145,300 dosage units

h. Perhaps even more significant than the enormous amount of oxycodone Respondent shipped to this store despite the information provided by the Chief of Police to its pharmacists and most senior leaders, is the fact that the dispensing records for both Oviedo Walgreens pharmacies show that on multiple occasions, they each dispensed additional prescriptions of commonly diverted narcotics to the same individuals who they knew had been previously arrested for drug offenses at their pharmacies. I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substances Act.

17. While the detailed information provided by the Chief of Police put Respondent and its parent company on notice of actual diversion occurring at the two Oviedo pharmacies, Respondent had ample other indications that its pharmacies were direct and significant contributors to the epidemic of prescription drug abuse and diversion in Florida, yet it largely ignored these indicators, at all levels of the corporate structure. An inexhaustive description of some of these indicators are the following:

a. On September 27, 2010, a pharmacist working at Walgreens # 04727 in Ft. Pierce reported to law enforcement that he mistakenly provided an extra 120 dosage units of 15 milligram oxycodone to a customer. When the pharmacist tried to call the customer to request he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and views the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens # 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.

b. On November 4, 2010, a Walgreens # 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom, leaving behind evidence indicating she had smoked the oxycodone. Despite this incident, Walgreens # 04727 continued to fill the same customer's oxycodone and alprazolam prescriptions on several occasions in November and December 2010 and January 2011.

c. On December 21, 2010, a pharmacist employed by Walgreens Pharmacy # 3629 in Hudson, Florida reported to the Pasco County (Florida) Sheriff's Office that an individual had attempted to fill a prescription for 270 dosage units of thirty milligram oxycodone, but ran from the pharmacy after learning the pharmacy had contacted law enforcement, suspecting the prescription was a forgery. Despite this incident, the same pharmacy that reported this customer to the Sheriff's Office in December continued to fill the same customer's oxycodone prescriptions in February, March, April, May and October of 2011.

18. On or about March 2011, corporate officials at Walgreens headquarters in Illinois initiated a Florida pharmacy store review initially entitled "Focus on Profit" and later changed to "Focus on Compliance." The purpose of this review was to address the "significant increase in the number of [Schedule II controlled substance] prescriptions we are filling in [Florida]" after the October 2010 change in Florida law regarding pain clinics. The initial pilot survey asked the following questions, amongst others: "Do pain management clinic patients come all at once or in a steady stream?" and "Do you see an increase in pain management prescriptions on the day the warehouse order is received?" On May 17, 2011, in an email with the subject heading "Florida Focus on Profit," a Walgreen Co. corporate attorney reviewed the survey and regarding these two questions, stated "*If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.*" The surveys that ultimately were used in the Focus on Compliance initiative did not contain those questions. By omitting these questions in order to avoid gathering information pertinent to whether or not pain clinic patients were engaged in diversion, the Walgreens Corporation and Respondent as a corporate subsidiary, ignored its statutory and regulatory obligation to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. *See* 21 U.S.C. § 823(b) and (e).

19. Apparently as part of this "Focus On Compliance," Walgreens sought to develop and implement "Oxycodone Action Plans" within its districts in Florida in an attempt to reduce the volume of oxycodone dispensing on behalf of pain clinics. For store # 3629 in Hudson, the plan devised by District Pharmacy and Loss Prevention supervisors in a memo dated August 23, 2011 included *"contacting the Jupiter warehouse and designating order limits for Oxycodone."* The plan, effective immediately, was to "limit" the Hudson store to orders of no more than 100 bottles of 100 count 30 milligram oxycodone. Notwithstanding the memo and the plan to limit store #3629's purchases to no more than 100 bottles, Respondent subsequently

shipped the following orders to store 3629:

Date	Bottles	Dosage Units
09/26/11	331	33,100
10/10/11	371	37,100
11/29/11	200	20,000
12/06/11	113	11,300
12/13/11	150	15,000

Respondent's inability to enforce a very simple, modest limitation on this one pharmacy is further evidence of its failure to maintain effective controls against diversion, even in the rare instance when it tried to do so.

20. In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores. Additionally, in late May, 2012, approximately seven weeks after Administrative Inspection Warrants were served on six Walgreens retail pharmacies and Respondent, Walgreens suspended dispensing of Schedule II drugs as well as Alprazolam and Carisoprodol at these six pharmacies and two others. In my assessment of the imminent danger posed by Respondent's continued registration, I have considered these remedial measures, as well as Walgreens' claims that it continues to revise its suspicious order reporting system to prevent the excesses that occurred in 2010 and 2011. In my judgment, and in the exercise of the discretion afforded me by 21 U.S.C. § 824(d), the danger posed by Respondent's continued registration is only slightly mitigated by the dispensing restrictions enacted at these eight pharmacies.

21. To reiterate, my concerns with Respondent's distribution practices are not limited to the six Walgreens pharmacies discussed herein. Respondent distributes to over 800 other retail pharmacies in Florida alone, many of which dispense oxycodone in amounts far in excess of the U.S. and Florida averages and which also experienced dramatic increases in their distribution of oxycodone from at least 2009 to the present. No fewer than 43 Walgreens pharmacies in Florida purchased in excess of 500,000 dosage units of oxycodone in 2011, despite a national average of approximately 74,000 dosage units for all U.S. pharmacies and an average of approximately 110,00 dosage units for all Florida Walgreens pharmacies. Florida remains the epicenter of this country's prescription drug abuse problem and notwithstanding the cessation of Schedule II dispensing at eight of its retail customers, Respondent remains the top distributor of the most dangerous prescription drugs in Florida, and still has not made a single suspicious order report in calendar year 2012.

22. Through May of this year, Respondent's customers included 44 Walgreens retail pharmacies on the list of the 100 top oxycodone purchasing pharmacies in Florida.[2] Respondent continues to distribute large amounts of oxycodone while it appears to continue to misunderstand or ignore its obligation to maintain effective controls against diversion by reporting suspicious orders and conducting due diligence on its customer stores to verify the legitimacy of their orders. Thus, the fact that Walgreens stopped selling Schedule II controlled substances to a handful of retail pharmacies – virtually all of which Walgreens also knew were themselves under DEA investigation at the time Walgreens stopped distributing to these pharmacies – does little to mollify my concerns about the danger posed by Respondent's continued operation. The nature and significance of the problems revealed by DEA's investigation indicate that Respondent's anti-diversion measures are inadequate generally; the problems do not appear to be limited to the pharmacies discussed herein. Consequently, I believe that Respondent's continued operation poses an imminent danger to public health and safety.

23. Voluntary dispensing restrictions enacted either in anticipation of, or in reaction to regulatory action, do not indicate to me that Respondent and its parent company have recognized and adequately reformed the systemic shortcomings discussed herein. On the contrary, when a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its anti-diversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens' part as to its obligations as a DEA registrant.

24. My confidence in Walgreens' remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. Walgreens pledged in this MOA to enact a compliance program at all of its retail pharmacies to detect and prevent diversion of controlled substances and to implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens' effort to enact such a program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion. That Walgreens would actively seek to avoid documenting evidence of possible diversion in its "Focus on Compliance" in Florida immediately after entering this MOA, further contributes to my preliminary finding that Respondent's continued registration during

[2] By way of comparison, only two other national or regional chain pharmacies have stores on this list, one of which has four stores in the top 100, while the other has three.

the pendency of this proceeding constitutes an imminent danger to the public health and safety.

IN view of the foregoing, and based on information before the Agency as of the issuance of this notice, it is my preliminary finding pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), that Walgreens' continued registration is inconsistent with the public interest. Under the summarized facts and circumstances described herein, it is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse in Florida, that Respondent's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0277752 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.[3]

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Walgreens possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Walgreens's DEA Certificate of Registration RW0277752 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Walgreens decline to file a request for a hearing or, should Walgreens request a hearing and then fail to appear at the designated hearing, Walgreens shall be deemed to have waived the right to a hearing and the DEA may cancel

[3] I have primarily addressed Schedule II controlled substances based on Walgreens' representations that Respondent no longer distributes controlled substances other than Schedule II. This should not be construed as an indication that DEA has concluded that Respondent's distribution practices relating to non-schedule II controlled substances conform to all applicable requirements and obligations. To the contrary, many of the problematic distribution practices noted herein would raise imminent danger concerns with respect to non-Schedule II controlled substances if Respondent were to continue to distribute them.

such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.

Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Scott Lawson, Counsel for the Government
Jonathan Novak, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.